

IN THE CLAIMS:

Please amend the claims as follows.

1. (Currently Amended) A hand-operated drug delivery device for delivering to a patient a drug composition from a container which contains the drug composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container, wherein the device comprises comprising:

a dispensing unit adapted to receive the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug composition is dispensable from the device, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and

a removable casing unit for the dispensing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet;

and wherein:

the dispensing and casing units have securing features for releasably, fixedly securing the units together; and

the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;

the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;
in the closed state, the casing unit is configured to enclose the dispensing unit
with the container received therein; and

the dispensing unit is hand-operable to apply the actuating condition to the container ~~when fixedly secured to the casing unit and, when the dispensing unit is~~ independent from the casing unit.

2. (Canceled)

3. (Previously Presented) The device of claim 1 which is hand-held.

4. (Original) The device of claim 3 in which the device is adapted to be held by the casing unit when assembled with the dispensing unit.

5. (Canceled)

6. (Currently Amended) The device of claim [[5]] 1 adapted so that, when the casing unit is held by a hand of a patient, the hand of the patient is also able to operate the actuating mechanism of the dispensing unit.

7. (Canceled)

8. (Canceled)

9. (Previously Presented) The device of claim 1 wherein the container has a plurality of doses of the drug composition and is fitted with a dose counter mechanism, and wherein the dispensing unit has a dose counter advancing mechanism adapted in use to advance the dose counter mechanism when the actuating condition is applied by the dispensing unit to the container.

10. (Currently Amended) The device of claim 9 wherein ~~the actuating condition is movement of a first part of the container relative to a second part and the actuating mechanism of the dispensing unit is able to effect said relative movement and in which the dose counter advancing mechanism has a mechanical feature which engages the dose counter mechanism to advance it on relative movement of the first part of the container to the second part thereof.~~

11. (Original) The device of claim 10 in which the mechanical feature is a post.

12. (Previously Presented) The device of claim 10 in which the mechanical feature is a part of a rack-and-pinion mechanism, the other part being in the dose counter mechanism.

13. (Previously Presented) The device of claim 1 in which the outlet forms a part of a nozzle arrangement in the dispensing unit for directing the drug composition to the patient on application of the actuating condition to the container.

14. (Currently Amended) The device of claim [[7]] 1, wherein the second part of the container presents an outlet of the container.

15. (Previously Presented) The device of claim 13 wherein, the outlet of the container is held stationary by the nozzle arrangement.

16. (Currently Amended) The device of claim [[7]] 1, wherein the second part is a valve which is moved between a closed position and an open position on relative movement with the first part.

17. (Original) The device of claim 16, wherein the container is an aerosol container with the first part a canister.

18. (Previously Presented) The device of claim 1 further comprising the container and the drug composition therein.

19. (Original) The device of claim 18 in which the drug composition is for the treatment or prophylaxis of a respiratory disease or disorder.

20. (Previously Presented) The device of claim 1 which is an inhalation device or an intranasal device.

21. (Previously Presented) A drug delivery system comprising the device of claim 1 and at least one further dispensing unit, the dispensing units being interchangeable with one another.

22. (Currently Amended) A method of manufacturing a hand-operated drug delivery device for delivery of a drug formulated in a drug container which is adapted to be placed in a dispensing mode on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container, the method comprising the steps of:

providing a dispensing unit for receiving the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container which has an actuating mechanism for applying the actuating condition thereto and an outlet through which the drug formulation is dispensed on application of the actuating condition to the container, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and

separately providing a casing unit adapted to fixedly hold the dispensing unit such that the drug is dispensable from the container by the dispensing unit when held by the casing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet;

and wherein:

the dispensing and casing units have securing features for fixedly securing the units together;

the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;

the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;

in the closed state the casing unit is configured to enclose the dispensing unit with the container received therein; and

the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit.

23. (Canceled)

24. (Currently Amended) The method of claim 22 in which the drug delivery device is hand-held-and-hand-operable.

25. (Previously Presented) The method of claim 22 in which the dispensing unit is provided with at least a part of a dose counting mechanism.

26. (Previously Presented) The method of claim 22 in which the drug container has a dose counter and the dispensing unit has a dose counter advancing mechanism for advancing the dose counter on application of the actuating condition.

27. (Original) The method of claim 26 in which the dose counter advancing mechanism is a mechanical mechanism.

28. (Original) The method of claim 27 in which the dose counter advancing mechanism is a mechanical member in the casing unit which interengages with the dose counter to advance it on application of the actuating condition.

29. (Currently Amended) The method of claim 28 in which the mechanical member is a rack rack-like member.

30. (Canceled)

31. (Currently Amended) The method of claim [[30]] 22 in which the dispensing unit has a valve stem support for receiving a valve stem of a valve

mechanism of the container, relative movement of the container to the dispensing unit causing depression of the valve stem for release of a dose of the drug from the container.

32. (Previously Presented) The method of claim 22 in which the outlet of the dispensing unit is an exhaust duct for channeling the drug to the external environment when released from the container.

33. (Previously Presented) A drug delivery device formed by the method of claim 22.

34-35. (Canceled).

36. (New) The device of claim 1, wherein the casing unit comprises a container member which defines a cavity in which the dispensing unit is releasably, fixedly securable, and a cover member which is movably mounted on the container member for movement between closed and open positions relative to the cavity to respectively place the casing unit in the closed and open states.

37. (New) The device of claim 36, wherein the cover member is adapted to cover the outlet of the dispensing unit in the closed position and to uncover the outlet in the open position.

38. (New) The device of claim 36 wherein the dispensing unit is adapted to receive the container such that the first part is accessible to a digit of a patient's hand to enable the digit to move the first part relative to the second part and wherein the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part.

39. (New) The device of claim 38, wherein the cover member is adapted to cover the first part of the container when in the closed position and to uncover the first part when in the open position.

40. (New) The device of claim 1 wherein the dispensing unit is adapted to receive the container such that the first part protrudes therefrom.

41. (New) The device of claim 1 wherein the casing and dispensing units are releasably and fixedly secured together, optionally with a container received in the dispensing unit.

42. (New) The device of claim 18 wherein the dispensing unit is adapted to receive the container such that the first part is accessible to a digit of a patient's hand to enable the digit to move the first part relative to the second part and wherein the casing

Serial No.: 10/534,383

unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part.